PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: L. Paskar

SERIAL NO.: 09/931,466

FILED: 8/16/2001

FOR: Catheter with Out-of-plane Configurations

GROUP ART UNIT: 3762

EXAMINER: M. Bockelman

DOCKET NO.: 74442.01

Confirmation No. 3794

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is in furtherance of the Notice of Appeal, filed in this case on January 28, 2004.

The fees required under § 1.17, and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate. (37 CFR 1.192(a)).

This brief contains these items under the following headings, and in the order set forth below (37 CFR § 1.192(c)).

I. REAL PARTY IN INTEREST

The final page of this brief bears the practitioner's signature.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the party named in the caption of this brief, namely Larry D. Paskar, M.D.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal:

there are no such appeals or interferences.

III. STATUS OF CLAIMS

The status of the claims in this application is:

A. Total Number of Claims in Application

The total claims in the application are 1-34.

B. Status of all the Claims

1. Claims cancelled: 8, 9, 17, & 18.

2. Claims withdrawn from consideration but not cancelled: 1-7, 23, 25, 27 & 30.

3. Claims pending: 10-16, 19-22, 24, 26, 28, 29, & 31-34.

4. Claims allowed: None.

5. Claims rejected: 10-16, 19-22, 24, 26, 28, 29, & 31-34.

C. Claims on Appeal

The claims on appeal are 10-16, 19-22, 24, 26, 28, 29, & 31-34.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to final rejection.

V. SUMMARY OF THE INVENTION

The claims on appeal are all in general directed to methods using combination catheters to form "out-of-plane" shapes.

As will become apparent below, the prior art cited by the Examiner is primarily directed to pointing rather than shaping. And none of the art teaches the unexpected result—the formation of out-of-plane shapes when curved distal end portions of inner and outer elements interact—that form the basis of these claims. From two relatively simple elements—an inner element and an outer tube, Dr. Paskar (the present inventor) has developed a catheter that may be shaped into numerous shapes that in the prior art are achievable only by using a plurality of separate, pre-shaped catheters.

Claim 10 is illustrative of these claims. It requires a catheter tube having a distal end portion fixed in a first curve and disposing an inner medical element in the catheter tube. The claim further requires fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed

substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

This out-of-plane feature is illustrated below. Fig. 15 from the present application is an elevation in which the inner medical element 35 is coming out of the plane of the paper. Fig. 15A is a top plan view in which "P" is the plane of the paper in Fig. 15 and inner medical element 35 is clearly illustrated as coming out of the plane P. Fig. 15B is a perspective line drawing showing various out-of-plane shapes achievable by the present invention. It should be appreciated that out-of-plane shapes are useful not because they point in particular directions (a simpler shape pointing in the same direction can always be found), but because those shapes provide an "anchoring" or "wedging" effect that maintains the combination catheter in a desired position in the body. As will appear, the prior art cited against these "out-of-plane" claims are directed to aiming, not shaping.

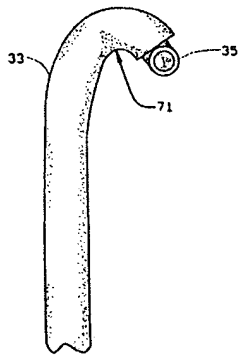


FIG. 15

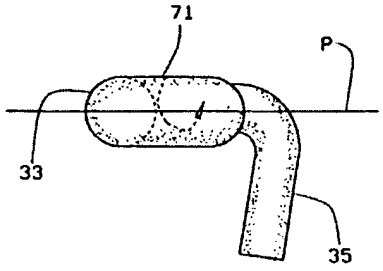


FIG. 15A

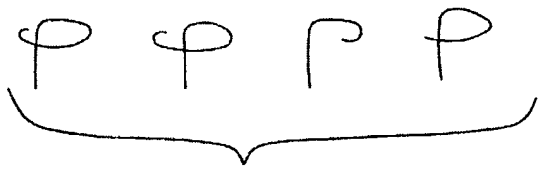


FIG. 15B

Front Elevation **Top Plan** **Line Drawings of Out-of-Plane Shapes**

In these figures, the portion of the catheter tube adjacent the distal end of the catheter tube defines a distal end portion of the catheter tube 33, said distal end portion assuming and maintaining a curved configuration such that the distal end portion of the catheter

tube is disposed substantially in a first plane. The first plane P is illustrated in Fig. 15A of the present application, above. Note that the distal end portion of catheter tube 33 is disposed in plane P, while the distal end portion of inner element 35 is disposed substantially out of plane P.

In these figures, the inner medical element 35 is disposed in the lumen of the catheter tube, said inner medical element has a distal end portion (the distal end portion of the inner medical element is illustrated in Fig. 15A) disposed substantially in a second plane (which is clearly shown in Fig. 15A). The inner medical element 35 is also specified as being positioned with respect to the catheter tube 33 such that the first plane P is disposed at a significant angle with respect to the second plane.

When the inner catheter or element is fixed at some intermediate rotational position, such as ninety degrees, with respect to the distal end portion of the outer tube, as illustrated above, the out-of-plane shapes of the present invention result. The curved nature of the inner element in this circumstance causes the exposed end of the inner element to be substantially out of the plane P containing the distal end portion of the outer tube. A whole family of these "out of plane" curves can be achieved as desired by the user by curving the outer tube more or less and exposing more or less of the inner catheter or element as illustrated above in Fig. 15B. Figs. 15-15B illustrate an important and unexpected feature of the present invention—rotational change in the relationship of an inner element with a distal curved portion and an outer tube with a distal curved portion change the shape of possible catheter configurations obtainable so that out-of-plane shapes are achieved.

At an interview in one of the parent cases, models were demonstrated to the Examiner of the present application illustrating the various families of curves achievable with the present invention. An offer to leave the models with the Examiner was declined by the Examiner. Subsequently, models were sent to the Examiner and applicant has repeatedly offered to demonstrate those models to the Examiner. Those offers, and multiple requests for interviews, have been refused. The models will greatly facilitate the Board's understanding of the issues on this appeal, as will the enclosed DVDs demonstrating a computerized simulation of the use of the models. (The DVDs contain exactly the same material as a videotape previously provided to the Examiner.) A hearing before the Board to explain these issues and the patentable subject matter is respectfully requested.

VI. ISSUES

A. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 102(b) (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Voda (U.S Pat. No. 5,445,625) or Weldon U.S Pat. No. 5,195,990) and Cho (U.S Pat. No. 5,109,830).

B. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), Cho (U.S. Pat. No. 5,109,830), and Takahashi reference manual.

C. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Ganz et al. (U.S. Pat. No. 4,430,083) in view of Sylvanowicz, Cho and Takahashi page 42.

D. Whether claims 10-16, 19, 24, 26, 28, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Cho (U.S. Pat. No. 5,109,830) in view of Ueda and Takahashi page 66.

E. Whether claims 21, 22 and 29 are unpatentable under 35 U.S.C. § 103(a) over Cho in view of Ueda and Takahashi page 66 and Komi (U.S. Pat. No. 4,979,496).

F. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over D'Amelio et al. or Costella in view of D'Amelio, each in further view of Ueda and Cho.

VII. GROUPING OF CLAIMS

A. With respect to the rejection of claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 under 35 U.S.C. 102(b) (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz, alone or in view of either Voda (U.S Pat. No. 5,445,625) or Weldon U.S Pat. No. 5,195,990) and Cho (U.S Pat. No. 5,109,830), claims 10, 12, 19, 20, 21, 22 stand or fall together; claims 11, 24, 26, 28, 33 and 34 stand or fall together; claim 13 stands or falls alone; claim 14 stands or falls alone; claim 15 stands or falls alone; claim 16 stands or falls alone; claim 29 stands or falls alone; claim 31 stands or falls alone; and claim 32 stands or falls alone.

B. With respect to the rejection of claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), Cho (U.S. Pat. No. 5,109,830), and Takahashi reference manual, claims 10, 12, 13, and 19 stand or fall together; claims 11, 24, 26, 28, 33 and 34 stand or fall together; claim 14 stands or falls alone; claim 15 stands or falls alone; claim 16 stands or falls alone; claim 20 stands or

falls alone; claim 21 stands or falls alone; claim 22 stands or falls alone; claim 29 stands or falls alone; claim 31 stands or falls alone; and claim 32 stands or falls alone.

C. With respect to the rejection of claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 under 35 U.S.C. 103(a) over Ganz et al. (U.S. Pat. No. 4,430,083) in view of Sylvanowicz, Cho and Takahashi page 42, claims 10, 12, 19, 20, and 23 stand or fall together; claims 11, 24, 26, 28, 33 and 34 stand or fall together; claim 14 stands or falls alone; claim 15 stands or falls alone; claim 16 stands or falls alone; claim 21 stands or falls alone; claim 22 stands or falls alone; claim 29 stands or falls alone; claim 31 stands or falls alone; and claim 32 stands or falls alone.

D. With respect to the rejection of claims 10-16, 19, 24, 26, 28, and 31-34 under 35 U.S.C. 103(a) over Cho (U.S. Pat. No. 5,109,830) in view of Ueda and Takahashi page 66, claims 10, 12, 13, 14, 33 and 34 stand or fall together; claims 11 and 28 stand or fall together; claim 15 stands or falls alone; claims 19, 20 and 26 stand or fall together; claim 24 stands or falls alone; claim 31 stands or falls alone.

E. With respect to the rejection of claims 21, 22 and 29 under 35 U.S.C. § 103(a) over Cho in view of Ueda and Takahashi page 66 and Komi (U.S. Pat. No. 4,979,496), claim 21 stands or falls alone; claim 22 stands or falls alone; and claim 29 stands or falls alone.

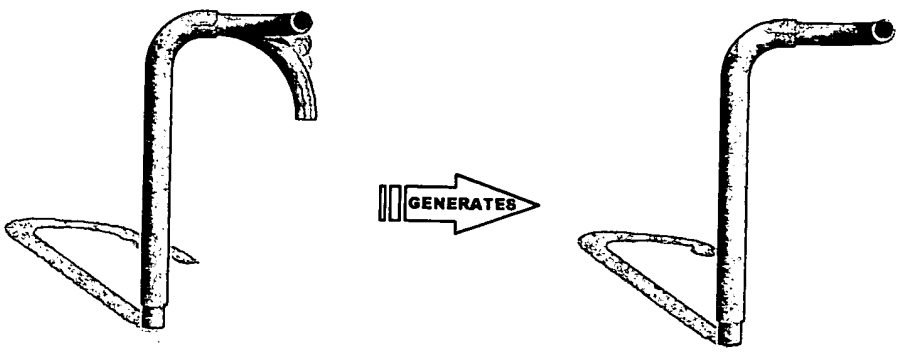
F. With respect to the rejection of claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 under 35 U.S.C. 103(a) over D'Amelio et al. or Costella in view of D'Amelio, each in further view of Ueda and Cho, claims 10, 12, 13, 14, 16, 19, 20, 21, 22, and 32 stand or fall together; claims 11 24, 26, 28, 33 and 34 stand or fall together; claim 15 stands or falls alone; claim 29 stands or falls alone.

VIII. ARGUMENTS

The Examiner has cited ten separate references in making six separate rejections of the claims. The MPEP, § 706.02 is very clear on this point, stating, "Merely cumulative rejections, i.e., those which would clearly fall if the primary rejection were not sustained, should be avoided." The same section of the MPEP also states, "Prior art rejections should ordinarily be confined strictly to the best available art." The only conclusion that can be reached from the Examiner's failure to heed these admonishments is that none of the rejections have merit.

In addition to the multiple rejections mentioned above, one of the rejections is presented in an alternative format (i.e., anticipated or obvious). Each rejection has also been presented as a "blanket rejection" (i.e., lacking explanation as to the relevance of the reference to each claim and an analysis of the elements of the claim in view of that reference). As a result, the grounds of rejection for each claim cannot be ascertained. Accordingly, the Examiner has failed to provide a prima facie case against patentability of any of the claims. Applicant traverses these rejections, as discussed below, but asserts that the presentation of multiple rejections under alternative theories is merely indicative of the presence in the art of similar devices.

The fundamental difference between the prior art and the present invention may be more readily understood by considering the following drawings, which illustrate the presently claimed formation of an out-of-plane shape by the interaction of two curves:



"B"
Out of plane

By rotating the inner element 90 degrees from the downward facing position shown to the left in the drawings above, one generates the out-of-plane shape shown to the right. This should be contrasted with the prior art in which the distal end of the outer tube is straight. Rotation of the inner catheter with respect to the outer (straight) outer tube does not, and cannot, result in an out-of-plane shape, as illustrated by the drawing below:

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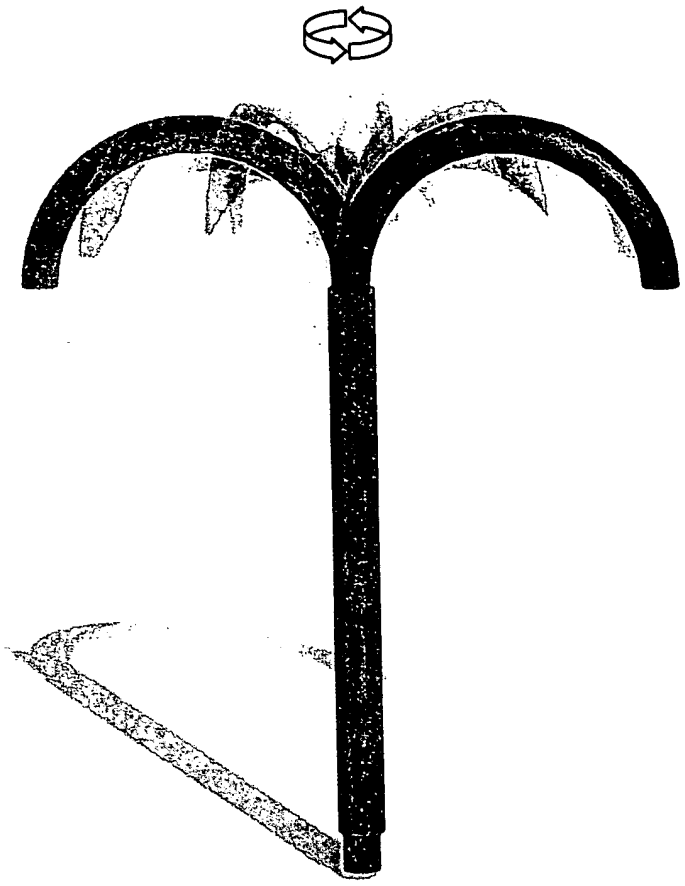
Prior Art



As will appear below in the discussion of the various rejections, the Examiner's approach below was legally and fundamentally flawed. The Examiner repeatedly ignored fundamental limitations of the claims. This is illustrated in the Examiner's rejection of the claims under § 103 over the Sylvanowicz reference. For example, claim 10 clearly requires that the "distal end portion" of the catheter tube assume and maintain a curved configuration—the claim requires "**said catheter tube having a distal end portion fixed in a first curve** such that the distal end portion of the catheter tube defines a first plane". As the drawings from Sylvanowicz clearly show and the specification explicitly states (col. 6, lines 55-56), the distal end portion 62 of catheter tube 52 in Sylvanowicz is

straight not curved. The Examiner erroneously frees himself from this limitation by selecting some other arbitrary portion of the Sylvanowicz catheter tube which is curved.

The Examiner's approach of ignoring claim limitations is fundamentally flawed and is repeated throughout the Office action. Specific examples are discussed in the discussions of the rejections below.

The Examiner also errs frequently in his conclusions that something is "inherent" in the cited art. A most egregious example of this is found in the Examiner's conclusion that the "out-of-plane" feature of certain of the claims is inherently present in the cited art, specifically Sylvanowicz. This conclusion cannot be true, as shown by the Examiner's actions in one of the parent applications of the present application. In application Serial No. 07/834,007, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

> "The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. The out-of-plane feature is not inherent and, therefore, Sylvanowicz does not teach the out-of-plane feature of these claims.

This example of misconstruing a reference solely for the purpose of rejecting patent claims is improper and should not be condoned. Other examples of misconstruing the references are found throughout the detailed discussions of the rejections below.

Although the types of errors committed by the Examiner are numerous, another significant one is that in the obviousness rejections the Examiner has completely failed to

show any motivation in the art for making the modifications and combinations he suggests. This error is repeated throughout the obviousness rejections. It is only through improper use of hindsight, by using the present invention, that the Examiner is able to make the suggested combinations.

In summary, the Examiner in the Office action below routinely ignored claim limitations, mischaracterized the art, and postulated motivation to modify and combine the art where none existed. All the rejections should be reversed.

VIII.A. REJECTIONS UNDER 35 U.S.C. § 102

A. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 102(b) (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Voda (U.S Pat. No. 5,445,625) or Weldon U.S Pat. No. 5,195,990) and Cho (U.S Pat. No. 5,109,830).

With respect to these claims, the Examiner has taken the position that Sylvanowicz inherently shows the "out of plane" feature (although it is never discussed) and the "fixing" requirement of the claims. It should be noted that

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1368, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). 'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *Id.* at 1269, 20 USPQ2d at 1749."

In re Robertson, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). As will be shown, the Examiner has at most shown a possibility that Sylvanowicz has these features. Certainly there is no showing (1) that the out of plane feature is "necessarily present" in Sylvanowicz, or that (2) "it would be so recognized by persons of ordinary skill in the art." Nor has he shown that the fixing feature is necessarily present or that its presence would be recognized for those of ordinary skill in the art.

The Examiner asserts that in moving the Sylvanowicz catheter from the figure 12 position to the figure 14 position it must inherently pass through an out of plane configuration.

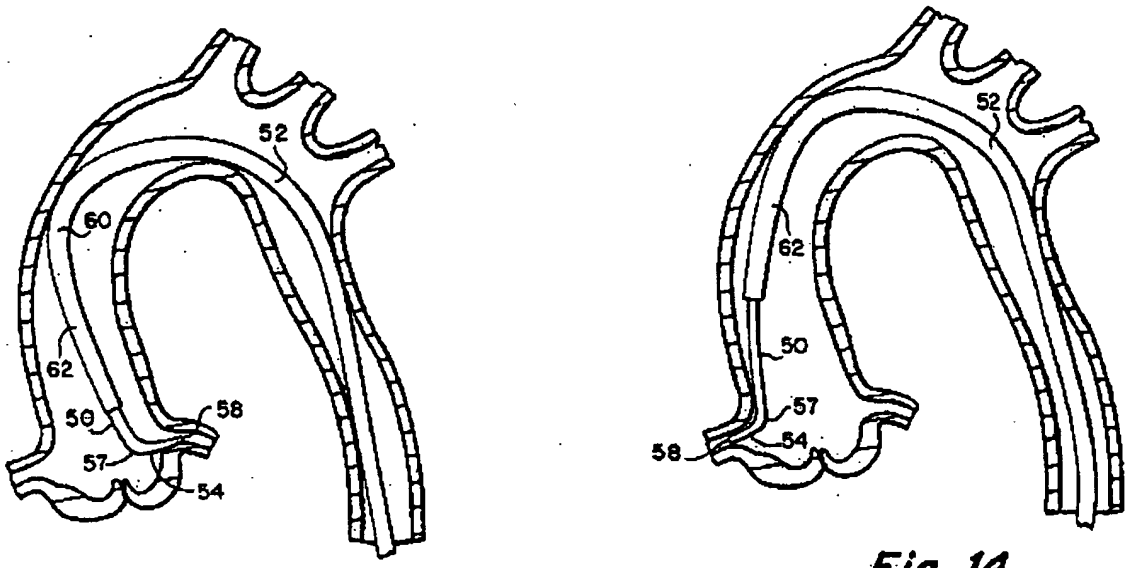


Fig. 14

But this approach ignores a fundamental limitation of the claim. Claim 10 (and the other claims at issue) clearly requires that the "distal end portion" of the catheter tube assume and maintain a curved configuration. Note the reference is not to the "distal portion", but

to the "distal end portion". The Examiner's interpretation of the Sylvanowicz reference might have some merit if the limitation were the "distal portion", since everything distal of the proximal end is a distal portion, but it is clearly erroneous since the limitation is the "distal **end** portion". "End" has a well-recognized meaning, which the Examiner has routinely ignored. The Examiner refers not to the distal end portion of Sylvanowicz, but rather to some intermediate portion that suits his purposes.

As the above drawings from Sylvanowicz clearly show, the distal end portion 62 of catheter tube 52 in Sylvanowicz is straight in Fig. 12 and in Fig. 14, and there is no indication that the distal end portion 62 is curved at any time in moving from the Fig. 12 position to the Fig. 14 position. In fact, Sylvanowicz specifically identifies portion 62 as "The outer tube has a relatively large radius curve 60 formed adjacent its distal end and a **straight distal segment** 62 extending from the curved portion 60." (col. 6, ll. 53-56)(Emphasis added). Thus, the distal segment of Sylvanowicz **that includes the end**, i.e., the distal end portion, is straight, not curved. Since the distal end portion of the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curves which results in the inner element being thrown out of plane with respect to the outer catheter tube.

The Examiner takes the position that in moving from the Fig. 12 to the Fig. 14 position, the catheter must go out-of-plane. But that conclusion is false. The present claims clearly define the plane with respect to the **curved distal end portion** of the outer catheter, not with respect to the outer catheter as a whole. It is only by ignoring the plain language of the claim and of Sylvanowicz ("**straight** distal segment 62") that the Examiner is able to reach his erroneous conclusion as to what must happen.

Similarly, the Examiner recognizes that the configuration of Fig. 12 in Sylvanowicz is planar, but appears to take the position that the other configuration (that of Fig. 14) must be out-of-plane. The Examiner is incorrect, as can be easily demonstrated. In col. 7, lines 25-30, and 46-52 of Sylvanowicz, formation of the configuration for entering the right coronary artery ostium (the configuration of Fig. 14 is described, as follows:

> "Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which cause a repositioning of the **distal portion of the inner catheter** so that it **points toward the right coronary ostium**."
>
> "By withdrawing the outer tube proximally to reposition the primary curve, **the distal segment 62 [of the outer tube]** is reoriented and **points toward the right coronary ostium**. Thus, when extended, the position of the protruding distal portion of the inner catheter shifts from the position as shown in FIG. 12 toward a position toward the right coronary ostium." (Emphasis added)

Note that the inner catheter in Sylvanowicz is disposed in the outer tube and exits from the distal tip of distal end segment 62 (see Fig. 14, for example). These elements are, therefore, co-linear at the point where the inner catheter exits the outer tube. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the rights coronary ostium, then those two elements **must be in the same plane**. If they were not co-planar when in the Fig. 14 configuration, it would be physically impossible for both the distal segment 62 of the outer tube and the distal portion of the inner catheter to both point toward the right coronary ostium.

This difference between Sylvanowicz and the presently claimed invention is seen more clearly by examining the following figures from the present application.

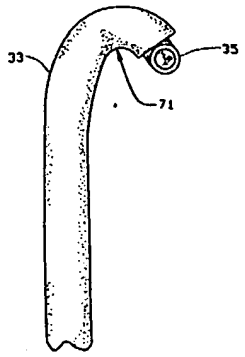


FIG. 15

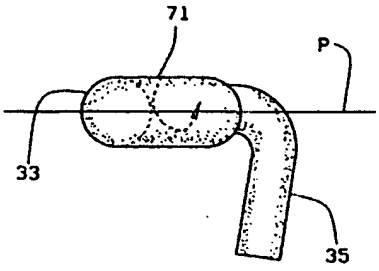


FIG. 15A

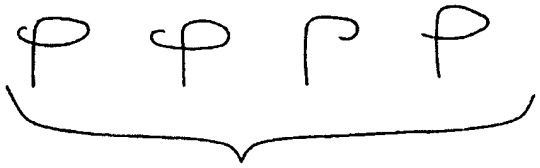


FIG. 15B

In Fig. 15 of the present application, the distal end portion of the catheter tube is clearly curved in the plane of the paper and the inner curved element, as a result, has its distal end portion thrown out of the plane of the paper (as shown in Fig. 15A). The two curves (that of the curved distal end portion of the catheter tube and that of the curved distal end portion of the inner element) are in two different planes, which provides an overall out-of-plane shape as illustrated in Fig. 15B.

Contrast this with Sylvanowicz in which a single plane always contains the straight distal end portion 62 of the catheter tube and curved distal end portion 54 of the inner element, **even as the inner element is rotated from one position to the next**. The result is different in Sylvanowicz because the distal end portion 62 of the catheter tube is straight, not curved as required by the present claim. An infinite number of planes pass through the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the distal end portion 54 of the inner element lies in one of those planes.

Moreover, no one has recognized the huge advantages of being able to obtain this entire family of "out of plane" shapes from two curvable elements. In fact, such a construction is immensely useful. It permits two planar elements (the inner element and the outer tube) to interact to provide an out-of-plane position for the distal end. It should be recognized that out-of-plane positioning is extremely useful in the human body. Yet Sylvanowicz fails to even hint at this feature. The claimed feature is simply not inherent in Sylvanowicz.

The Examiner's inherency argument is further undercut by the history of the present invention. In Serial No. 07/834,007, one of the parent applications of the present application, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

> "The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. Sylvanowicz simply does not teach the out-of-plane feature of these claims.

The Examiner is simply wrong. He has ignored claim limitations fundamental to the claimed invention, and he has "found" inherency where none in fact exists. These claims are allowable over Sylvanowicz for all these reasons. Because of both the language of the claims and the relevant Federal Circuit precedent, this claim is allowable over Sylvanowicz.

The Examiner has also taken the position that Sylvanowicz shows the "fixing" requirement of these claims in the presence of an anti-leak device, even though that

device permits relative rotation and translation of the two tubes in Sylvanowicz. How a device that permits (and in fact is designed to permit) relative rotation and translation between these two elements can be said to "fix" those two elements is truly a mystery. For example, Sylvanowicz contains, among others, the following passages concerning translation and rotation of the inner catheter with respect to the outer tube while both are disposed in the human body:

Col. 7, lines 20-23	"Thus, the inner catheter may be rotated along its longitudinal axis so that it is directed selectively toward the left coronary ostium or the right coronary ostium."
Col. 7, lines 23-30	"Additionally, the configuration of the distal portion of the catheter assembly may be controlled by withdrawing the catheter outer tube proximally over the inner catheter. **Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which causes a repositioning of the distal portion of the inner catheter so that it points toward the right coronary ostium.**" (Emphasis added)
Col. 7, lines 43-48	"Thus, as illustrated in Fig. 13, the outer

	tube 52 has been withdrawn so that the position of the primary curve relative to the distal end of the catheter is moved proximally. By withdrawing the outer tube proximally to reposition the primary curve, **the distal segment 62 is reoriented and points toward the right coronary ostium.**" (Emphasis added)
Col. 7, lines 52-57	"The inner catheter 50 may be rotated about its longitudinal axis approximately 180° to direct the distal tip 58 toward the right coronary ostium so that as the distal portion of the catheter 50 continues to shift it will bring the tip 58 into the right coronary ostium."

Note that all of this relative manipulation (rotation and translation of the outer tube and inner catheter take place in the human body, **yet the patient does not bleed to death.** Apparently (and obviously) the hemostasis valve relied upon by the Examiner is on the entire time. The hemostasis valve, therefore, does not provide the required fixing.

Claim 11, which depends from claim 10, further requires "fixing the inner medical element rotationally with respect to the catheter tube." That feature is totally absent from Sylvanowicz. There is no indication in the present application that applicant

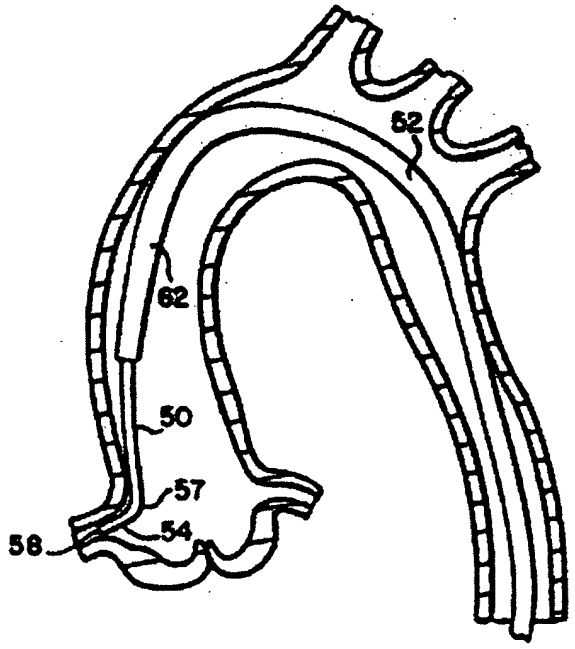
is using "fixing" in any way other than its ordinary or customary meaning—namely, making firm or stable or stationary. The anti-leak device of Sylvanowicz does not fix the inner tube with respect to the outer tube, and hence does not meet the limitation of these claims.

In fact, the Examiner in earlier prosecution of these claims admitted that the anti-leak device allows relative movement between the relevant parts stating, "even though the user may still be able to turn the inner catheter with respect to the outer." Sylvanowicz clearly contemplates such rotation, so there is no question that the user "may" be able to rotate the inner catheter with respect to the outer in Sylvanowicz. Sylvanowicz clearly contemplates that such rotation and translation will take place. Since Sylvanowicz teaches directly away from the claimed invention, these claims directed to fixing the inner element with respect to the outer catheter tube are separately patentable for these reasons.

Claim 13 also depends from claim 10 and further provides that at least one of the catheter tube and the inner medical element are remotely controllable to form curves in their distal end portions. Sylvanowicz completely lacks this feature—neither tube in Sylvanowicz is remotely formable into a curve, so the § 102 rejection of this claim is baseless.

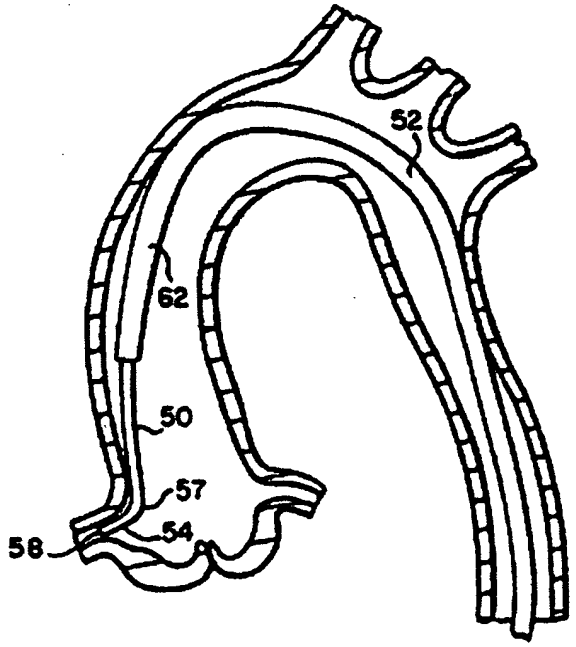
Claims 14-16 also depend from claim 10 and are allowable therewith. In addition, claim 14 provides that "the first curve has a first radius of curvature and the second curve has a second radius of curvature, both curves being disposed a distance from the respective distal ends of the catheter tube and the inner medical element not substantially greater than three times the smaller of the first and second radii of

curvature". As can be seen from the drawing below, there is no curve in the outer tube of Sylvanowicz that is located (measured from the distal tip) within three times the radius of curvature of the curve in the distal end portion of the inner tube. Thus, Sylvanowicz completely lacks this feature. This feature is important, because it is one way of measuring whether the two curves are capable of interacting to form the out-of-plane feature of all the present claims.



Claim 15 specifies that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. As discussed above, Sylvanowicz completely lacks such fixation, and certainly fails to teach fixation at an extreme angle such as ninety degrees.

Claim 16 is similar to claim 14 in providing a measure of how close the curves must be to the ends of their respective elements (and to each other), specifying: "wherein the first curve has a first arc length and the second curve has a second arc length, each curve being disposed from the distal end of its corresponding tube or element respectively a distance no greater than three times the smaller of the first and second arc lengths, further including the step of separating the first and second curves in operation by no more than three times the smaller of the first and second arc lengths." As can be seen from the drawing below, Sylvanowicz also lacks this feature.



Claim 19 is another independent claim that is allowable for essentially the same reasons as claim 10. Specifically, it requires "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element." As explained above, Sylvanowicz does not have the out-of-plane feature as claimed, and has no suggestion of using a catheter having such an out-of-plane configuration in a medical way.

Claims 20, 21, 22, 24, 26, and 32 depend from claim 19 and are allowable therewith. Claims 24 and 26 require proximal fixing, which, as explained above, is totally absent from Sylvanowicz.

Claim 28 is another independent claim. This claim includes not only the out-of-plane feature of claim 10, but also the fixing feature of claim 11. It is allowable for the same reasons as both of those claims.

Claim 29 is also independent and includes the out-of-plane and fixing requirements of claim 28. It also provides for forming the combination catheter into a second shape, in which the distal end of the combination catheter is also in an out-of-plane shape, and fixing the inner medical element against translation and rotation while the combination catheter is in that shape. Sylvanowicz lacks fixation in a single out-of-plane shape, so it certainly does not teach fixation in two different out-of-plane shapes. Claim 29 is allowable for all these reasons.

Claims 31, 33 and 34 depend from claim 10 and are allowable with that claim. Claim 31 further specifies that the second curve is disposed substantially out of the first plane by rotating the inner medical element with respect to the catheter tube. In

Sylvanowicz rotation of the inner tube does not create the claimed out-of-plane configuration, because the distal end portion of the outer tube is straight. Therefore, the requirements of claim 31 (disposed substantially out of the first plane) are not met. Claim 33 provides that the step of fixing includes proximally fixing the distal end of the combination catheter substantially out of the first plane. As explained above, Sylvanowicz completely lacks the feature of fixing the elements to fix the shape of the combination catheter. Claim 34 specifies that the step of fixing includes proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As explained above, Sylvanowicz lacks this feature since it clearly teaches both rotation and translation of the inner tube with respect to the outer tube and the anti-leak device does not prevent that movement.

Claim 32 depends from claim 19 and is allowable with that claim. Claim 32 is also allowable because it specifies that the forming step includes rotating the inner medical element with respect to the catheter tube.

For all these reasons, these claims are all allowable over Sylvanowicz.

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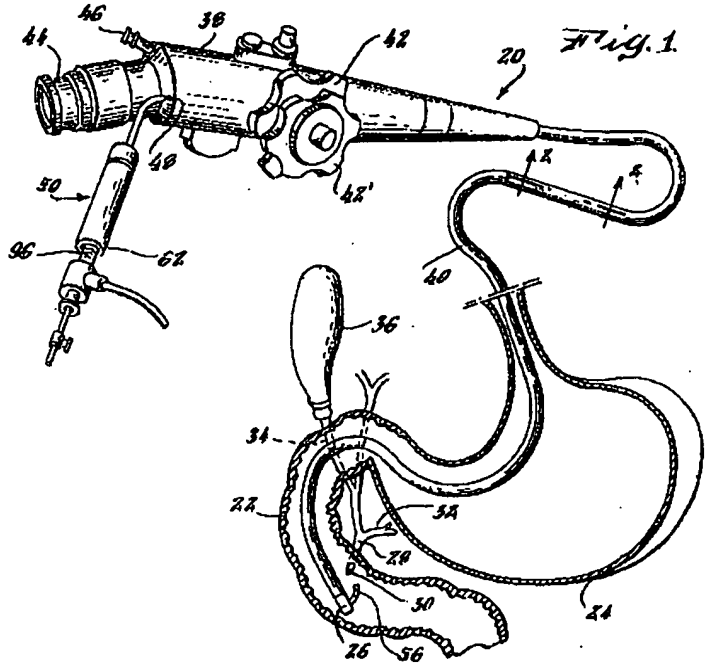
B. **Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), Cho (U.S. Pat. No. 5,109,830), and Takahashi reference manual.**

Petruzzi can best be understood from an examination of its drawings. Fig. 1 is set forth below:



As can clearly be seen in this drawing, Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element 56. As shown in Fig. 3, below, the inner element can be extended out through an opening in the side of endoscope 40 and its curve may be changed by means of a movable wedge 92.

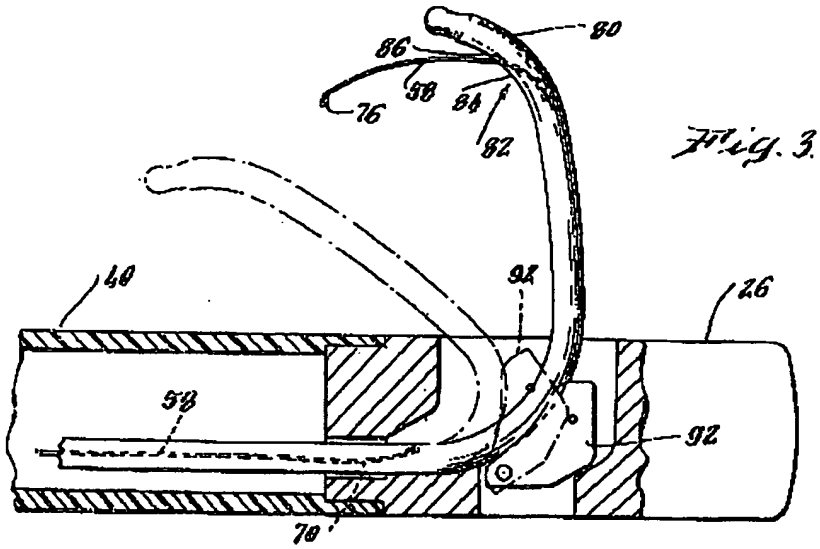


Fig. 3.

Curved element 56 and a tool 58 contained therein are shown in more detail in Fig. 3 from Petruzzi, set forth above (curved element 56 being unlabeled in Fig. 3, but being identified in Fig. 1). Note that there is no indication the inner element 56 in Petruzzi will occupy any plane other than the one defined by the longitudinal axis of the outer tube. In fact, in Fig. 1 of Petruzzi the window or opening in the endoscope (shown but not labeled in Fig. 3 above) through which member 56 extends cannot be seen, thereby indicating that the plane defined by the distal end portion of outer element is not in the plane of the paper, but rather is in some other plane—presumably the one including element 56 and a valve 30 known as the ampulla of Vater.

The Examiner takes the position that Petruzzi must show the claimed out-of-plane configuration of the present invention, stating:

"As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right

manner relative [corrected] to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner medical 56 60 be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the [ ] ampulla of Vater."

The reference to "60" in this statement by the Examiner is not understood since it appears that "60" is an internal, conductive control wire that has no bearing upon the claimed out-of-plane feature. More importantly, the Examiner is wrong. The drawings of Petruzzi, namely Fig. 1, which hide the opening in the endoscope that faces the ampulla of Vater are inconsistent with the Examiner's speculation but are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being "in plane", not out-of-plane as required by these claims.

Moreover, the claimed out-of-plane shape of the distal end in Petruzzi, as explained below, is unachievable since the distal end is straight, solid, and unbendable. This is shown in Fig. 3 of Petruzzi. That Figure is set forth below.

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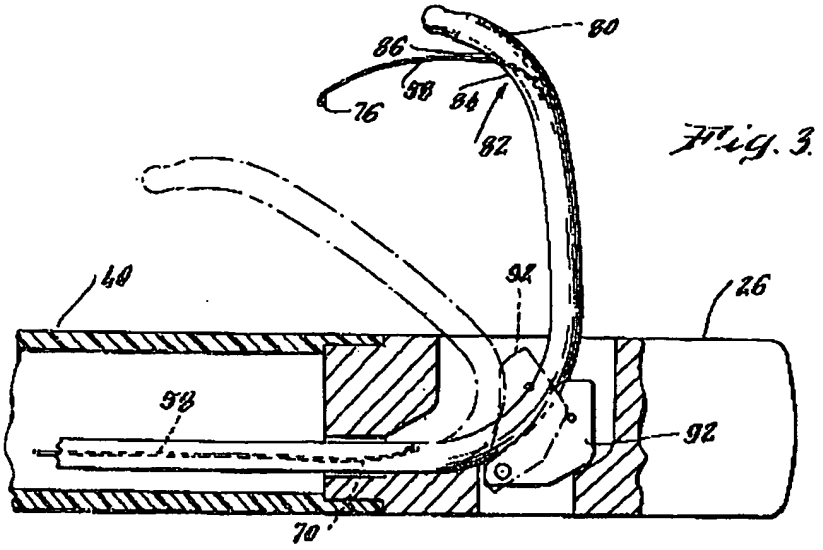


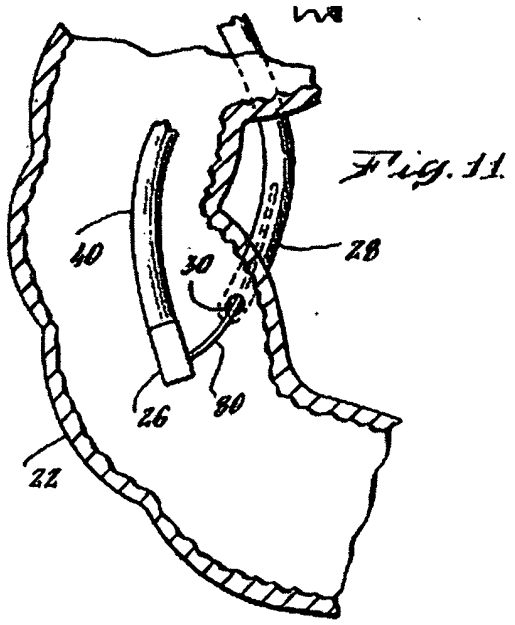
Fig. 3.

Note that there is absolutely no mechanism in Petruzzi to cause the distal end portion to bend in any way. It is solid. The inner catheter that comes out of the side of this straight, solid portion is bendable by the wedge 92, but there is no similar mechanism for forming a curve in the distal end portion of the outer tube. Note as well that the movement of element 82 in Petruzzi is in the plane of the window of the outer catheter. It appears that the structure of Petruzzi, as would be expected, in fact mechanically confines element 82 to stay in plane. Moreover, there is absolutely no structure provided to move element 82 out of that plane.

With the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by pointing the window of the endoscope straight toward the ampulla. This is a matter of basic physics. If the window of the endoscope were positioned in a left/right manner as theorized by the Examiner, the medial wall (and not the posterior wall containing the ampulla) would be visualized. In that case, since the ampulla would not be in sight, it could not be catheterized. If the window were not pointing at the ampulla,

the user would not have any idea where to direct the catheter. And if the catheter were disposed out-of-plane with respect to the window/ampulla plane, it would not (could not) go into the ampulla.

Importantly, one should note that one does not see the window in Fig. 1 or Fig. 11 of Petruzzi, which is totally consistent with the window and the optics facing the ampulla in the posterior wall—allowing the catheter to be extended *in the plane* of the window and ampulla so that all elements are clearly in a single plane. For convenience, Fig. 11 of Petruzzi is shown below:



With the Petruzzi device, unless the object (in this case the ampulla of Vater) is in line of sight view, it cannot be catheterized. The Examiner's theory of events—looking in one direction and catheterizing in another which you cannot see and do not know the location of—is impossible with the Petruzzi device. Petruzzi *could* show many things, but it does not show or suggest this invention.

Claim 10, as discussed above in connection with Sylvanowicz, is a method claim that requires fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As explained above, Petruzzi does not and cannot disclose this feature. In fact, endoscopes like those disclosed in Petruzzi are not designed for "fixing the distal portion of the inner medical element". Rather, endoscopes provide a stable platform from which an inner element is extended or moved to a desired position. "Fixing" the inner element with respect to the endoscope runs counter to the ordinary and normal operation of an endoscope. An inner element that is fixed with respect to the endoscope to form a shape (the present invention) cannot be extended or moved with respect to the endoscope (as is desired in conventional endoscope operation). Conventional endoscopes and the presently claimed invention are mutually exclusive.

Claim 10 also requires medically using at least one of the catheter tube or the inner medical element while the distal end of the inner medical element is disposed substantially out of the first plane. This is also absent from Petruzzi, since Petruzzi completely lacks the out-of-plane feature.

Apparently recognizing the weakness of this rejection, the Examiner tries to combine Petruzzi with **four** other references. As an initial matter, it should be noted that there is no motivation to combine Petruzzi with a single other reference, much less four such references. Nothing in Petruzzi or the art indicates that Petruzzi fails to achieve its purpose or could be improved. Yet the Examiner, using hindsight provided by the present invention, hypothecates a combination of Petruzzi with these other references.

That combination, even ignoring the absolute lack of any motivation to make it, must fail. The D'Amelio et al reference (U.S. Patent 4,659,195) unequivocally states that the two elements should not go out of plane, stating:

> "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39.

If the combination of Petruzzi and D'Amelio et al were to be made (despite the total lack of motivation), it would not result in an out-of-plane shape because D'Amelio et al teaches that it is imperative ("must") that the two tubes be "in the same plane". This reinforces applicant's argument above concerning the teaching of Petruzzi of planar operation.

Nor is the Examiner's rejection helped by U.S. Patent 4,617,914 to Ueda. Ueda discloses an "End Curving Device for Endoscope", but where is the motivation to provide such a structure for Petruzzi? The structure of Petruzzi is already complicated and crowded internally. Why would anyone want to make it more complicated when it apparently achieves its desired purpose? The only reason to make the combination suggested by the Examiner is the hindsight provided by the present invention. This is improper.

The Examiner also cites U.S. Patent 5,109,830 to Cho for the feature of "rotationally fixing and sealing the inner medical element relative to the outer tube body". It is respectfully submitted that the Examiner has misread Cho, and that up to this date the applicant has allowed him to do so without correction. Although it looks like inner catheter 5 in Cho is rotated from the position shown in Fib. 5b to the position shown in Fig. 5c, in fact that is not the case. Inner catheter 5 in Cho is "S-shaped" (see

col. 4, lines 34-35). To change the shapes from that shown in Fig. 5a to those shown in Figs. 5b and 5c, successively greater amounts of the inner catheter are extended longitudinally. See col. 4, line 51 to col. 5, line 9, which states:

> "The catheter system 1, however, is not limited through motion in a single straight direction. Rather, it may be, likewise, moved in either lateral direction (i.e. towards the right or left). FIG. 5b illustrates how the catheter system 1 may be moved in a right-hand lateral direction. More specifically, FIG. 5b shows how the catheter system may be oriented down a right-hand fork 30 of a body cavity. To move down this right hand fork 30, the inner catheter 5 is exposed to reveal only a right-hand curving portion of it. The entire catheter system 1 is then be moved forward which results in the inner catheter 5 forking to the right. The inner catheter 5 creates a steering to the right-hand fork 30 so that the outer catheter 15 tend towards the right-hand direction and conforms to the shape of the right hand fork 30 of the body cavity. The outer catheter 15 is designed to be flexible enough to conform to the shape of the body cavities in which it travels.
>
> "FIG. 5c illustrates how the catheter system can be navigated in the other lateral direction referred to as the left-hand direction. To achieve left hand navigation an additional portion of the inner catheter 5 is exposed relative to the outer catheter 15. This additional portion is oriented primarily in a left-hand direction. The catheter system is, thus, moved as previously described which results in movement along the left hand branch 32 of the body cavity."

Thus, the Examiner is completely wrong about what Cho teaches—there is no rotation whatsoever. Thus, in addition to the lack of motivation to combine Cho with the other

references, the rejection suffers from the additional defect of being factually inconsistent with the reference.

The Takahasi reference does not add anything that would indicate that Petruzzi is, or even could be, operated in the manner suggested by the Examiner.

Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith. In addition, claim 11 provides for fixing the inner medical element rotationally with respect to the catheter tube. The Examiner cites Cho for that feature, but as pointed out above, the Examiner has misread Cho. Claim 14 provides that the first curve (in the distal end portion of the outer element) has a first radius of curvature and the second curve (in the distal end portion of the inner element) has a second radius of curvature, both curves being disposed a distance from the respective distal ends of the catheter tube and the inner medical element not substantially greater than three times the smaller of the first and second radii of curvature, further including the step of separating the first and second curves in operation by no more than three times the smaller of the first and second radii of curvature. The Examiner takes the position the "The bends in the Petruzzi catheter as shown in figure 11 are both within 3 lengths of the small radii of curve." This statement ignores the fact that the distal end portion of the outer element in Petruzzi are straight, and appears to be incapable of bending. Moreover, the distal end portion of the inner element in Fig. 11 of Petruzzi appears to be straight as well. It is, of course, difficult to respond to a rejection that ignores the literal language of the claim limitations. Claim 15 provides that the second curve defines a second plane, the first plane being fixed at an angle of approximately ninety degrees with respect to the second plane. None of the

references show such a feature. And claim 16 is similar to claim 14, but defines the separation of the first and second curves in terms of arc length rather than radius of curvature. This feature, like that of claim 14, is totally lacking in Petruzzi. Claims 11-16 are allowable for all these reasons as well.

Claim 19 is an independent method claim that also requires the defined out-of-plane feature. It is, therefore, allowable for the same reasons as claim 10. Claims 20, 21, 22, 24, and 26 depend from or relate back to claim 19 and are allowable therewith. In addition, claim 20 includes the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane. None of the cited references disclose the out-of-plane feature, so they by definition lack the feature of using the combination catheter in a medical procedure while the distal end of the combination catheter is out-of-plane. The present invention allows the formation of various out-of-plane shapes in the body, as needed, for various medical procedures, and then the use of the formed shape in the medical procedure. The Petruzzi reference does not. Rather, it shows pointing in a desired direction and extending the inner catheter—not shaping. This feature is emphasized even more in claim 21 which further requires the step of reforming the distal end of the combination catheter into a substantially different shape, and in claim 22 in which the combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. Claim 24 provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. As explained above in connection with Sylvanowicz, this proximal fixing feature is not found in the art. (Note, for example, that in Cho the outer element 15

is straight, so it does not define the first plane and hence there can be no fixation of the distal end of the combination catheter substantially out of the first plane. Conversely, if the duodenoscope 51 is considered the outer tube, there is no mechanism for fixing the catheter with respect to the duodenoscope.) In addition, note that D'Amelio et al teaches proximal fixing against translational movement, but does not teach proximal fixing against rotation (which is required to fix "the distal end of the combination catheter substantially out of the first plane" as required by this claim. Claim 26 further provides for proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed immediately above, D'Amelio et al teaches translational fixing, but not rotational fixing. Claims 20, 21, 22, 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent method claim that includes the out-of-plane feature of claims 10 and 19, as well as the proximal translational and rotational fixing feature of claim 26. Claim 28 is, therefore, allowable for all the same reasons as those claims.

Claim 29 is an independent method claim directed to forming the combination catheter into first and second out-of-plane shapes and proximally fixing those shapes for periods of time sufficient to permit medical use. None of the references teaches the proximal fixing for even a single out-of-plane shape, much less two. More significantly, the prior art is mute concerning forming first and second out-of-plane shapes. Claim 29 is unquestionably allowable.

Claim 31 depends from claim 10 and is allowable along with that claim. It further provides that the second curve is disposed substantially out of the first plane by rotating

the inner medical element with respect to the catheter tube. Although the Examiner cites Cho for rotation, as pointed out above, the Examiner has misread Cho. None of the references disclose the out-of-plane feature, much less the relative rotation that causes it. Claim 31 is allowable for this reason as well.

Claim 32 depends from claim 19 and also is directed to the feature of forming the shape by rotating the inner medical element with respect to the catheter tube. The art, as discussed above in connection with claim 31, lacks this feature, so claim 32 is allowable for this reason as well.

Claims 33 and 34 depend from claim 10 and are allowable for the same reasons as that claim. In addition, claim 33 provides that the step of fixing includes proximally fixing the distal end of the combination catheter substantially out of the first plane. As discussed above, that feature is absent from the cited art. Claim 34 provides that the step of fixing includes proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed above, these feature is also absent from the art. Claims 33 and 34 are also allowable for these reasons as well.

C. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Ganz et al. (U.S. Pat. No. 4,430,083) in view of Sylvanowicz, Cho and Takahashi page 42.

The Examiner has completely misconstrued the Ganz et al. reference. He states:

"Ganz et al shows in figure 12 and 13, methods for catheterizing two passageways of the lower circumflex branch using a catheter using a planar outer catheter 11a (column 7 lines 7-20) **and an inner rotatable catheter 105**." (Emphasis added).

In fact Ganz et al. uses **two separate inner catheters to catheterize the two passageways.** These catheters are labeled 11a and 11b in Ganz. See col. 7, lines 24-33 for a description of inner catheter 11a, and col. 7, lines 45-57 for a description of inner catheter 11b. Element 105, referred to by the Examiner as the inner catheter is in fact merely a preformed bend in inner catheter 11a. See col. 6, lines 40-57, which state:

> "Figs. 6 and 7 show a catheter 11a which is identical to the catheter 11 in all respects not shown or described herein. Portions of the catheter 11a corresponding to portions of the catheter 11 are designated by corresponding reference numerals followed by the letter 'a'.
>
> "The only difference between the catheters 11 and 11a is in the configuration of the distal end portions. Specifically, the distal end portion 47 is straight, whereas the **distal end portion 47a has** two resilient orientation bend sections 101 and 103 and **a passage-seeking bend section 105** which is also resilient. The passage-seeking bend section 105 is **configured to seek out the left anterior descending coronary artery** 107(Fig. 12). The orientation bend **sections 101 and 103 automatically orient the passage-seeking bend section 105** when the **catheter 11a is used within an angiography catheter, such as an angiography catheter 57a** (Fig. 12) which is designed for exploring the left coronary arteries." (Emphasis added)

This passage starkly reveals the Examiner's errors.

1. Catheter 11a has a distal end section 47a that includes a bend section 105—"105" is not an inner catheter.

2. Catheter 11a is the inner catheter, disposed inside outer (angiography) catheter 57a—catheter 11a is not the "outer" catheter. (Perhaps the Examiner was misled by Fig. 12 which shows "57a" and "11a" pointing to the same element. Clearly, in view of the written description quoted above, the applicant was indicating that catheter 11a was **inside** catheter 57a, but this error is understandable if one fails to read the relevant portion of the reference.)

3. Orientation bends 101 and 103 cooperate with the bends in the outer catheter 57a to **automatically** orient the bend section 105 in the proper direction to seek out the left anterior descending coronary artery—the inner catheter is not designed to be rotatable, it is designed to emerge at a single, unchanged orientation. Perhaps this error is the most serious of all, for it completely misses the point of Ganz—the inner and outer catheters are shaped so that the inner catheter always emerges from the outer catheter in a predetermined, desired orientation. Ganz teaches exactly the opposite of the rotation feature of the present invention.

This third error leads to yet another error of the Examiner with respect to the Ganz reference. Rather than teach rotating inner catheter 11a to obtain the configuration of Fig. 13, Ganz teaches using a completely new inner catheter 11b to create that shape. Col. 7, lines 45 to 53 states:

"Fig. 8 shows a **catheter 11b** which **is identical to the catheter 11a, except** that the **bend section 105b is displaced 180 degrees from the bend section 105.** The catheter 11b can be used with the angiography catheter 57a as shown in Fig. 13 in the same manner as described above with reference to Fig. 12. In terms of

operation, the only difference is that the **bend section 105b emerges from the distal opening 65a approximately 180 degrees displaced from the bend section 105.**" (Emphasis added).

4. Contrary to the Examiner's statement, therefore, there are two different inner catheters used in Ganz—catheter 11a for use as shown in Fig. 12 and catheter 11b for use as shown in Fig. 13. Note that the quoted passage states that catheters 11a and 11b are identical except for bend sections 105 and 105b. This means that both have the orientation bend sections 101 and 103 that orient the inner catheter with respect to the outer catheter 57a. But they differ in that the bend sections 105 and 105b are basically curved in opposite directions, so that as they emerge from the outer catheter they emerge pointing in basically opposite directions.

The Examiner's rejection based upon Ganz et al. is, therefore, based on a completely incorrect reading of the reference.

The Examiner also states in this rejection that "While Ganz does not teach rotationally fixing the inner catheter, it would have been obvious in view of Cho and Sylvanowicz to provide a sealing as well as locking force to maintain placement of the catheter during drug delivery." The error in this reasoning with respect to the sealing function is discussed above in connection with Sylvanowicz. It is compounded in the present rejection because the very structure of Ganz is designed to insure that the inner catheter emerges from the outer catheter in a desired orientation. Where is the motivation for fixing when the inner and outer catheters are designed to prevent rotation without fixing? Moreover, the Examiner's conception of what is actually happening in these devices is flawed. The pressure during drug delivery using these devices is, if you think

about it, wholly internal to the inner element. The drugs are not forced between the inner element and the outer tube. Therefore, locking forces as suggested by the Examiner are not necessary since there is no increased force between the inner element and the outer tube during drug delivery.

The Examiner further states in this rejection that "The curves on the inner catheter are remotely controllable by rotating and sliding the catheters with respect to each other in a manner as taught by Sylvanowicz or otherwise obvious." This statement is demonstrably false as explained above. The inner catheter in Ganz et al. is not designed to rotate. It is designed to assume a single orientation with respect to the outer catheter. Ganz et al. completely lacks the remote control feature.

Finally, the Examiner is in error in this rejection where he states, "In regard to those claims that require first and second out of plane configurations (claim 28 [sic]) the examiner considers it obvious to provide the first treatment of figure 12 followed by a second treatment in figure 13 and in view of Sylvanowicz, to use the[sic] same inner catheter rotated." Note that Ganz et al. uses two different inner catheters to accomplish this—not one. Where is the motivation to combine Ganz et al. with Sylvanowicz? In fact, the combination of Ganz et al. with Sylvanowicz cannot possibly work, because the orientation bends 101 and 103 of the inner catheter (under the teachings of Ganz et al.) will insure that the inner catheter cannot be successfully rotated to the opposite position. That is why Ganz et al. uses two different inner catheters. The impossibility of the Examiner's proposed combination surely weighs heavily against it.

Turning to the claims, claim 10 requires "fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is

disposed substantially out of the first plane". The Examiner admits in the Office action that Ganz et al. does not show or suggest fixing. And the impossibility of the combination suggested by the Examiner reveals that it would not be obvious to look to Cho or Sylvanowicz for such fixing. Moreover, there is nothing in this art to suggest that the distal end portion of outer catheter 57a in Ganz et al. is not planar with both inner catheter 11a (in Fig. 12) and inner catheter 11b (in Fig. 13). Note that the distal end portion of Ganz et al. distal of bend 67a in Fig. 12 does not point in the same direction as that same portion in Fig. 13. It is respectfully submitted that this change in position is certainly sufficient to allow the corresponding inner catheters (11a and 11b) to both be coplanar with the distal end portion of outer catheter 57a in their respective positions. The Examiner's position could have merit if the drawings of the distal end portions of outer catheter 57a were the same in Figs. 12 and 13. But they are not. Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith. Claim 11 further specifies that the inner medical element is fixed rotationally with respect to the catheter tube. As discussed above, Ganz et al. lacks this feature, there is no motivation to combine the references as suggested by the Examiner to add it, and even if the combination were made it would not work. Claim 13 specifies that at least one of the catheter tube and the inner medical element are remotely controllable to form curves in their distal end portions. As discussed above, there is no remote control (pullwire) in these references.

Claim 14 requires that the first and second curves are separated in operation by no more than three times the smaller of the first and second radii of curvature. The smaller

radius of curvature in Ganz et al. is that of bend 105 and bend 105b. The curve in outer catheter 57a appears to be separated from the curve at bend 105 (and that at bend 105b) by roughly ten times the relevant radius of curvature. Claim 15 provides that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. There is no indication of any out-of-plane shape in Ganz et al., much less one of 90 degrees. Claim 16 requires that the first and second curves in operation are separated by no more than three times the smaller of the first and second arc lengths of those curves. Like claim 14, the arc length of bends 105 and 105b are the relevant arc lengths, and the curve in outer catheter 57a is substantially farther than three arc lengths away from the curve of bends 105 and 105b. These claims are allowable for these reasons as well.

Claim 19 is an independent claim that requires "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element." As explained above, there is no showing that Ganz et al. provides such an out-of-plane feature. Claim 19 is allowable for this reason. Claims 20-22, 24 and 26 depend from and relate back to claim 19 and are allowable therewith. Claim 21 further requires reforming the distal end of the combination catheter into a substantially different shape. As discussed above, Ganz et al. requires a different inner catheter 11b to form the substantially different shape. The present invention is, therefore, a substantial improvement over Ganz et al. Claim 22 depends from claim 21 and further specifies that the reformed combination catheter is used in a medical procedure while the distal end of the combination catheter is in the

reformed shape. Ganz et al. requires two separate inner catheters (11a and 11b) to obtain two different shapes. The present invention merely reforms the catheters already in place. The vast savings in time and expense, and the resulting improvement in patient outcomes should be apparent.

Claim 24 depends from claim 19 and provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. Ganz et al. does not have this feature (and, as explained above, neither do the other references). Moreover, there is no reason to add such a feature to Ganz et al.—also as discussed above. Claim 26 similarly requires proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. This feature is not shown or suggested in this art.

Claim 28 is an independent claim that includes the step of "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element", and the step of "proximally fixing the inner medical element against translation and rotation with respect to the catheter tube." As discussed above, Ganz et al. lacks the out-of-plane feature and lacks any fixing feature. There is no motivation in the art to combine the references as suggested by the Examiner, and in fact the structure in Ganz et al. teaches away from such a combination. And the secondary references do not show these features anyway. Claim 28 is allowable for all these reasons.

Claim 29 is another independent claim. It specifies two different out-of-plane shapes and using each. It also requires proximally fixing the inner medical element

against translation and rotation with respect to the catheter tube after each shape is formed. The art, as discussed above, fails to show or suggest even a single out-of-plane shape coupled with proximal fixing. It consequently is completely silent concerning forming a second out-of-plane shape with the same combination catheter and proximally fixing when that shape is achieved. Claim 29 is allowable for all these reasons.

Claim 31 depends from claim 10 and is allowable therewith. It also provides that the second curve is disposed substantially out of the first plane by **rotating** the inner medical element with respect to the catheter tube. Ganz is designed to function in a way that the rotation required by claim 31 cannot occur. Since this feature is directly the opposite of what is taught by Ganz, claim 31 is allowable for this reason as well.

Claim 32 depends from claim 19 and is allowable for the same reasons as that claim. It further requires that the forming step includes rotating the inner medical element with respect to the catheter tube. As discussed above, Ganz et al. is designed to insure that such rotation does not occur and that the inner catheter emerge with a single, predetermined orientation. Claim 32 is allowable for all these reasons.

Claim 33 depends from claim 10 and is allowable therewith. It further specifies that the step of fixing includes proximally fixing the distal end of the combination catheter substantially out of the first plane. Such a proximal fixing is absent from this art (as explained above), so claim 33 is allowable for this reason as well.

Claim 34 also depends from claim 10 and is allowable for the same reasons as that claim. Claim 34 further requires that the step of fixing includes proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

As discussed above, proximal fixing is not shown or suggested by this art. Claim 34 is allowable for all these reasons.

D. Whether claims 10-16, 19, 24, 26, 28, and 31-34 are unpatentable under 35 U.S.C. 103(a) over Cho (U.S. Pat. No. 5,109,830) in view of Ueda and Takahashi page 66.

The Examiner takes the position that these claims are unpatentable over Cho in view of Ueda and Takahashi. In particular, Ueda is cited for fixing a curve in the distal end portion of an endoscope. This is relevant because claim 10, inter alia, requires

> "a catheter tube . . . having a distal end portion **fixed in a first curve** such that the distal end portion of the catheter tube defines a first plane".

The citation to Ueda is a recognition on the Examiner's part that the primary reference, Cho, does not fix the distal end portion in a first curve to define a plane. Without Ueda, therefore, the Examiner's rejection fails completely. But the Ueda reference cannot properly be combined with Cho.

The Cho reference, in particular Figs. 6 and 7 referenced by the Examiner, teaches a three part device: an outer duodenoscope 51, and a two-part catheter system 1 or 3. An examination of the Cho specification reveals that catheter system 1 consists of an outer tube 15 and an S-shaped inner catheter 5, while catheter system 3 consists of an outer tube 42 and an S-shaped inner fiber optic element 40. It certainly appears from Cho that these three elements are sufficient to intubate the desired passageways. Why would anyone be motivated to add further complexity to the Cho duodenoscope 51? They would not. Moreover, there is no indication that the duodenoscope and the catheter are moved together. Conventionally, with a duodenoscope or other endoscope, the scope

provides a stable platform from which the catheter is moved. There is no indication in Cho of anything other than this conventional operation.

The Examiner cites class/subclass schedule 600/148 for motivation to add pull wires to Cho, but the mere fact that relatively simple endoscopes can (and do) have pull wires is no motivation for increasing the complexity of the system shown in Cho. There is no indication in Cho that the outer tube 51 in Cho has a curve fixed therein as required by the present claim (in fact, the same is true of intermediate tubes 15, 42), so it cannot define the claimed first plane. Since the claimed first plane is not defined, the inner element of Cho also fails to meet the requirement of claim 10 that the distal end portion of the inner medical element be fixed "in a second curve such that the distal end of the inner medical element is **disposed substantially out of the first plane**". Since there is no first plane, the plane of the curved distal end portion of the inner element in Cho can never be out of the first plane. Moreover, there is nothing in Cho to suggest that, even if the outer tube were fixed in a curve, the inner element has a curvature that is out-of-plane with respect to the (hypothetical) outer tube curve. The invention is simply neither shown nor suggested by Cho.

Claim 10 is allowable for all these reasons.

Claim 11 depends from claim 10 and is allowable therewith over these references. Claim 11 also provides for "fixing the inner medical element rotationally with respect to the catheter tube." There is no showing in these references of any way to fix the inner tubes rotationally with respect to the duodenoscope, or indeed to fix either of the two parts of the inner tubes rotationally with respect to the duodenoscope. Moreover, that would be contrary to the conventional operation of endoscopes in general and

duodenoscopes in particular. This fixing step is fundamental to the invention of claim 11, for it allows the combination catheter to be shaped into the desired out-of-plane shape and then used in that shape.

Claims 12-16 also depend from claim 10 and are allowable therewith. Claim 15 provides that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. As discussed above, Cho completely lacks the first plane, and even if it could be read to disclose such a first plane there is no showing of a second plane at the extreme angle of 90 degrees with respect to the (hypothetical) first plane. Claim 15 is allowable for these reasons as well.

Claim 19 is an independent claim that requires a catheter tube having **a distal end portion fixed in a first curve such that** the distal end portion of the catheter tube **defines a first plane**. Claim 19 also requires forming the combination catheter (made up of the outer tube and the inner medical element) into a shape in which the distal end of the combination catheter is disposed **substantially out of the first plane** for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. Even if Cho could be read to disclose fixing the catheter tube to define the first plane (discussed above), it certainly has no disclosure of forming the distal end of the combination catheter "substantially out of the first plane" as required by this claim. Note, for example, that is Fig. 7 of Cho the inner element and outer tube 51 appear to be co-planar, and certainly are not "substantially" out-of-plane. Nor, is it proper to add Ueda to Cho to find such a feature. Cho could be used in a manner other than what it discloses, but it is only the hindsight afforded by the present invention that reveals these novel and unobvious features. Claim 19 is allowable for all these reasons.

Claims 20, 24 and 26 depend from claim 19 and are allowable therewith. In addition claim 24 provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. Since Cho does not disclose fixing the distal end of the combination catheter substantially out of the first plane (as explained above), it certainly fails to disclose **proximal** fixing to accomplish this. Claim 24 is allowable for these reasons as well.

Claim 28 is an independent claim. Like claim 10 it provides for fixing the distal end portion of the catheter tube in a first curve that defines the first plane. This feature is discussed above. Claim 28 further requires forming the combination catheter into a shape in which the distal end of the combination catheter is disposed **substantially out of the first plane** for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As discussed above Cho completely fails to disclose "substantial" out-of-plane configurations. Claim 28 also requires proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed above fixing the inner element with respect to the duodenoscope would be contrary to conventional operation. And fixing the elements of Figs. 5a-5c with respect to each other would not meet this limitation because the outer tube in that situation is straight, not curved.

Claims 31, 33 and 34 depend from claim 10 and are allowable therewith. Claim 31 provides that the second curve is disposed **substantially out of the first plane by rotating** the inner medical element with respect to the catheter tube. Cho lacks any teaching of exiting any plane by rotating the inner medical element with respect to the catheter tube. Claim 31 is allowable for all these reasons.

Claim 32 depends from claim 19 and is allowable therewith.

E. Whether claims 21, 22 and 29 are unpatentable under 35 U.S.C. § 103(a) over Cho in view of Ueda and Takahashi page 66 and Komi (U.S. Pat. No. 4,979,496).

The Examiner has also rejected claims 21, 22 and 29 over Cho, adding the Komi reference for a showing of reforming "the catheter in first and second out of plane configurations so as to access both the pancreatic and bile duct". The Examiner has misconstrued the Komi reference. Fig. 3 of Komi shows that the duodenum 100 is very large with respect to the size of insertion unit 2—insertion unit 2 has room to move around to access the various ducts. As a result, the insertion unit is capable of (1) being in the same plane as guide tube 9 when intubating the bile duct and (2) being in a different single plane as the guide tube 9 when intubating the pancreatic duct. That this reading of Komi is correct is shown by Fig. 2, which shows that the insertion channel 3 (in which the guide tube moves) goes straight out the side of the insertion unit 2. As a result, the guide tube 9 exits the insertion unit in the same plane defined by the insertion unit. Since the Examiner is wrong about Komi, the rejection of all three claims fails.

In addition, claim 21 provides that distal end of the combination catheter is reformed into a "substantially different shape". The variation in shape of the distal end of the "combination catheter" in Komi—the combination catheter being the insertion unit and the guide tube 9—can hardly be said to be "substantial". The variation in shape between that required for intubating the bile duct and that required for intubating the pancreatic duct are so minor that the user must rely on radiography to determine which duct has been entered. See, for example, col. 6 lines 28-32 of Komi, which states:

"When the guide tube (9) placed into the papillae (101) above and below is to be inserted further, **it must be confirmed whether it has been inserted into the bile duct (103) or into pancreatic duct** (102) or how far the tip of the guide tube (9) has been inserted." (Emphasis added)

The process being described by Komi is not the same as that perceived by the Examiner. In Komi, minor variations in position cause either the bile duct or the pancreatic duct to be intubated. The actual duct intubated must, therefore, be confirmed. The Examiner, on the other hand, believes Komi teaches reforming "the catheter in first and second out of plane configurations so as to access both the pancreatic and bile duct." The "substantially different shape" limitation of claim 21 is completely absent from Komi (and the other references). Claim 21 is allowable for these reasons as well.

Claim 22 depends from claim 21 and is allowable therewith. It further specifies using the combination catheter in a medical procedure while the distal end of the combination catheter is in the reformed shape.

Claim 29 is an independent claim which also requires two out-of-plane shapes. Even if Komi showed one out-of-plane shape (which it does not), it certainly does not show two. Nor does Cho. Claim 29 goes on to require "forming the combination catheter into a second shape, different from the first shape" and "proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed in the second shape." Neither Komi nor Cho teach proximal fixing for two different shapes. Neither reference teaches two out-of-plane shapes in any case. Claim 29 is allowable for all these reasons.

F. Whether claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are unpatentable under 35 U.S.C. 103(a) over D'Amelio et al. or Costella in view of D'Amelio, each in further view of Ueda and Cho.

The Examiner states that "D'Amelio teach inner and outer articulating devices that may be locked so as to prevent rotation and translation in a similar fashion as Cho. The Examiner is wrong. Presumably, the Examiner is also taking the position that D'Amelio et al. shows or suggests the out-of-plane configurations claimed in the present claims, although this actual rejection (paragraph 8 of the Office action) makes no mention of an out-of-plane feature. Again, applicant is forced to guess as to the exact basis for the rejection.

In fact, D'Amelio et al. is fundamentally different from the presently claimed invention. D'Amelio et al. requires four (4) operating cables (pull-wires) 64 to manipulate the flexible end member 60 of a borescope 34 for inspecting a jet engine. The reason for four cables is stated in the following passage from D'Amelio et al.:

> "With the cables 64 placed at spaced circumferential locations around the inner surface 66, the distal collar 58 can be moved in as many directions as there are cables. Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides movement in four different directions lying in two different intersecting planes."

If D'Amelio et al. were actually shaping and forming as required by the claims of the present application, only one of the pull-wires would be needed (as in the present application). The other three would be superfluous. Similarly, if

D'Amelio et al. were shaping and forming as required by the present claims, two pull-wires would be more than sufficient. Yet D'Amelio et al. uses four. D'Amelio et al. is clearly directed to a very different device being used for a very different purpose.

As an aid to understanding the D'Amelio et al. reference, the following chart is provided which sets forth relevant passages from D'Amelio et al. and their relevance to the features of the present claims, with emphasis added:

Passage from D'Amelio et al.	**Relevance to Present Application**
"A problem arises in using presently available flexible devices for the internal inspection of complex articles of manufacture such as interior regions within jet engines. For example, certain compartments within the engine, such as the aforementioned regions within the burner cans and the turbine, are at present effectively inaccessible to viewing by an inspector. Such inaccessibility is the case even with the use of an inspection device such as an endoscope because the articulation of the inspection device requires some sort of guiding surface, such as the interior wall of the colon, to orient and support the inspection device. In contrast to the colon of the human body, a jet	This passage teaches that the D'Amelio et al. device, unlike most medical catheters, is designed to function in an environment "characterized by relatively open spaces and few appropriate supporting surface[s] readily available to guide the objective end of the inspection device." This is in contrast to the present invention. Various out-of-plane shapes interact with the walls of various human vessels. The present invention permits the formation of these shapes in situ, while the D'Amelio et al. reference teaches avoiding the walls. Note that even in the case of colonoscopy, the D'Amelio et al. reference teaches the desirability of avoiding the colon

engine has **an interior characterized by relatively open spaces and few appropriate supporting surface readily available to guide the objective end of the inspection device**. In addition, presently known endoscope designs, even when used for their originally intended purpose, are not easily able to negotiate all colon configurations without **substantial risk of puncturing the colon wall**." Col. 2, lines 3-22.	wall. See, col. 2, lines 19-22.
"Additional **problems** with the **known devices** are that the guide tube can **only articulate in two directions**, i.e. in one plane, which makes it very awkward and time consuming to get the distal end thereof in the **proper location** for feeding the viewing scope through the crossover tubes. This is generally done by lining up in the plane by which articulation of the distal end thereof is possible and then jumping or jogging the cable around to exactly line it up **so that the viewing scope can be located correctly**. Finally, the known scopes cannot easily accomplish inspections of the	Teaches the desirability of being in the "center of the burner can" for inspection. Shows that the patent is directed toward positioning the distal end ("get the distal end thereof in the proper location") rather than forming a particular shape, such as the claimed out-of-plane shapes.

louvered section of the burner can or the first stage stationary vanes and first rotor as they **cannot be easily located in the center of the burner can** for ease of such inspection." Col. 3, lines 4-17.	
"The distal end is slidably inserted through a tubular elongated flexible guide member which has an operating head at a near end and a distal collar at a remote end capable of **deflecting in four discrete directions**. The objective assembly of the borescope is capable of deflecting in two discrete directions." Col. 3, lines 31-37.	Talks about deflecting in four discrete directions and two discrete directions. No hint that out-of-plane as defined in the claims is desirable or even possible with such a construction. D'Amelio et al. invention is thus directed to maximum flexibility in the placement of the distal end, not its shape.
"The device of the invention provides for a **four-way (two-plane) articulation** of the flexible guide tube whereas known devices provide for only a two-way (one-plane) articulation of the guide tube. As with the prior art, the present invention also provides for a two-way (one-plane) articulation of the viewing scope or borescope." Col. 3, lines 60-66	Talks about deflection in two different planes with the D'Amelio et al. device, but again totally fails to realize that one can achieve distal configurations that are out of either of those two planes.
"Since there are four cables at equally spaced	Teaches movement in four different directions

circumferential locations in the illustrated embodiment, that construction provides **movement in four different directions** lying in two different intersecting planes." Col. 6, lines 27-31.	lying in two different intersecting planes, but again fails to even hint that the distal end can be disposed out of either of those two intersecting planes. D'Amelio contemplates planar movement in either of two selected planes, but not an out-of-plane shape as defined by the claims.
"**Extension and retraction** of the telescoping support member 38, as shown in FIGS. 9A and 9B is effected by rotating knurled nuts 38A AND 38B to grasp and release the internal tubular members in the conventional fashion." Col. 6, lines 35-39	Knurled knobs 38A and 38B are taught as holding against longitudinal movement only. (Free to turn at another segment, which allows rotation.)
"However, it will be appreciated that even in the retracted position of the flexible body 42, the objective assembly 46 can still be manipulated to the dotted line positions indicated in FIG. 3A. In its **retracted position**, the objective assembly 46 may typically extend approximately 1.4 to 2.0 inches beyond the distal collar 58 and in the **extended position**, approximately 6 to 8 inches or longer beyond the distal collar 58." Col. 6, lines 57-65	Describes the longitudinally retracted and extended positions of the D'Amelio et al. device. Again, no reference to fixing the two parts of the device against rotation.

"The retention spring 68 is preferably fashioned from flat stock so as to occupy minimal space when viewing the tubular member 60 from an end. The retention spring thus serves to retain the operating cables 64 and their surrounding outer tubes in their proper respective positions even though **the borescope 34 is twisted relative to the tubular member 60**. Specifically, the retention spring 68 prevents the operating cables 64 from spiraling with the borescope 34 **as the latter is spun inside the tubular member 60**. In the absence of the retention spring 68, the operating cables 64 would tend to **spin** with the borescope 34 which would not only cause interference between the borescope and the tubular member 60, but also would cause unreasonable and unnecessary wear on the parts." Col. 7, lines 13-25.	Far from desiring fixing of the borescope of D'Amelio et al. against rotational movement, such rotational movement is desired to accomplish its purpose.
"These differences include the capability of the guide member 36 having four-way, that is, two-plane articulation." Col. 7, lines 30-32.	"Reference to "two-plane articulation" but no clue that out-of-plane shaping is possible.

"In a typical maneuver, as illustrated in FIG. 13, while the objective assembly 46 is viewing the liner of the burner can 74 opposite the igniter port 76, the distal collar 58 is articulated by means of the actuating knobs 62 and 63 to enable the objective assembly 46 to locate a crossover tube 78 between the adjacent burner cans 74. With continued manipulation by the operator of the inspection system 30, the distal collar 58 is moved closer to the crossover tube 78 as illustrated in FIG. 14 **while keeping the tube 78 in the center of view** of the objective assembly 46."	"Illustrates how the D'Amelio et al. device relies solely on optical feedback to place the device properly. Also illustrates that the location, not the shape, of the distal end is the only thing of interest to D'Amelio et al.
"During this entire procedure, areas of interest within the burner cans can be inspected by articulating the objective assembly 46 and the distal collar 58, feeding the system 30 to an extreme end of a burner can, then extending the objective assembly 46. The inspection itself is performed as the system 30 is withdrawn from each burner can. To inspect an area around a crossover tube through which the objective assembly 46 and distal collar 58 are	Again describes operation of the D'Amelio et al. device, and in particular teaches (with respect to Fig. 19) that the inner and outer elements "must articulate in the same plane." This is a clear teaching away from the present invention.

inserted is generally illustrated in FIG. 19. For this view, the objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 28-39	
"There are numerous advantages inherent in the present invention over the known devices. In the first place, the four-way articulation of the steerable flexible guide member 36 allows a quicker, more **precise positioning** of its distal end before the objective assembly 46 is extended. This is important because of the **different positional locations** between the igniter port 76 and the crossover tubes 78 and other elements to be inspected by the device." Col. 8, lines 40-48.	D'Amelio et al. is teaching positioning of the distal end—not shaping. D'Amelio et al. is indifferent to the shape of the device. Position is all that matters in the D'Amelio et al. patent.
"This is done by placing the distal end of a flexible guide member 36 **in the center of the burner can** 74 as illustrated by dotted lines in FIG. 1. The invention, by virtue of its four-way articulation, permits the distal collar 58 to be easily **placed in the center of the burner can** and then to **spin or rotate** the objective assembly 46, which is positioned near the	Teaches placing the end of the outer element in the center of the burner can (again placement only). Also teaches free rotation of the inner element with respect to the outer element (not rotational fixing). Articulation of the outer member in four directions (apparently never at the same time) is used solely to facilitate the placement of the end of the device in the center

louvered area 80, in a 360 degree arc so as to inspect each one of the louvers. This easily performed operation contrasts with the prior art constructions which are restricted by a two-way articulation at the end of their equivalent of the tubular member 60. Such prior art devices cannot be **positioned** very easily in the center of a burner can but must be **located in several positions** in order to inspect all of the louvers around the outside of the burner can." Col. 8, line 55 to col. 9, line 2.	of the burner can. At that point, the inner member is spun or rotated to observe all the louvers. This should be contrasted with applicant's out-of-plane feature, which would not provide this functionality. A catheter with an out-of-plane distal tip could not, by rotation of the inner element with respect to the outer, result in observation of the various louvers. This difference is fundamental. D'Amelio et al. is interested in positioning—the present invention is directed to shaping.
"It is also noteworthy that the first stage of the jet engine 32 can be much more easily viewed by the invention. This is depicted in FIG. 21 which illustrates the distal collar 58 being **precisely located within the burner can** next to the fixed guide vanes 82 of the first stage of the jet engine 32. In this manner, the objective assembly 46 can be fed through the vanes in a precise manner and displaced accurately adjacent the first stage rotor 84. The rotor can then be turned by hand for complete inspection by the system 30. While the prior art can	Teaches positioning in the center of the burner can for yet another inspection operation.

theoretically accomplish this end result, the fact is that in order to inspect the rotor 84 and the fixed guide vanes 82, the objective assembly 46 must repositioned several times because of the awkwardness in positioning it in the first place. This awkwardness results from the limited two way articulation system previously employed. Thus, the known inspection systems must work around the area to be inspected with several positions for the end of the guide tube. In contrast, the invention merely requires that the distal collar 58 be set **near the center of the burner can** so that when the objective assembly 46 of the borescope 34 is fully extended, it will be in the precise position to get into the rotor area." Col. 9, lines 3-26.	
"Also, it should be noted that when the control head 44 is moved relative to the operating head 56 and **spun or rotated** in a concentric manner with the tubular member 60, the proximal end thereof is relatively linear and rigid. Another element of the construction of	Again teaches free rotation of the inner element with respect to the outer element—not rotational fixing.

the present invention which adds considerably to the reliability of the invention is the provision of the retention spring 68 which eliminates potential problems of the operating cables 64 twisting with the flexible body 42 as the latter is **spun or rotated** inside the tubular member 60." Col. 9, lines 46-57.	

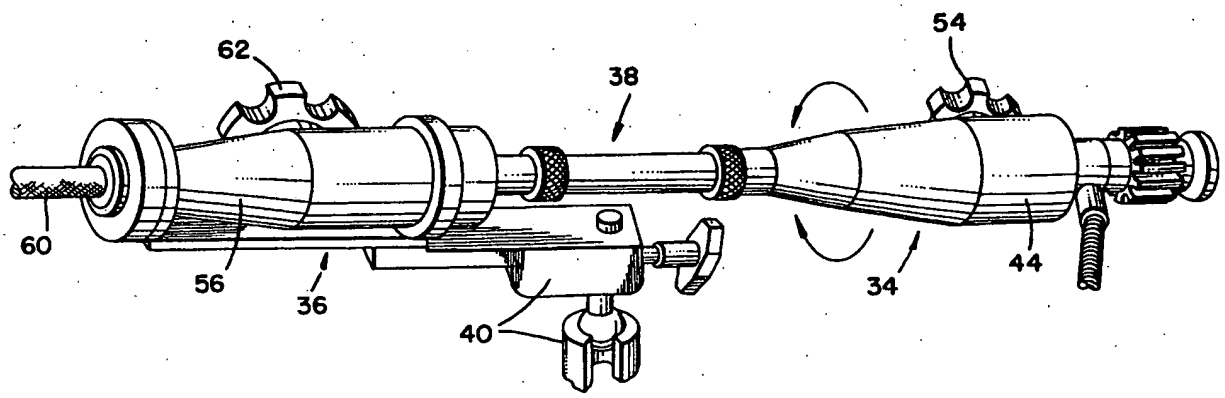
Preliminarily, it should be noted that there is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al. Moreover, the Examiner has not pointed to anything in other prior art which would suggest making any modifications to D'Amelio et al.

The Examiner does cite the US patent classification system and Ueda for braking systems to maintain articulated curves. Although that may be true in the abstract, it is hardly true in the context of the present rejection which includes D'Amelio et al. (Of course, as pointed out above, the Examiner misreads D'Amelio et al. to include preventing rotation.) D'Amelio et al., when correctly read, teaches free rotation because that is how it works—a can is entered and the device is spun through 360 degrees to inspect the can. Adding a device to fix D'Amelio et al. against rotation is like adding a device to a paving machine to put potholes in a road—no one trying to achieve the

desired result would do it. The Examiner's use of the US classification system could be appropriate in some other rejection, but not in a rejection that includes D'Amelio et al.

Turning to the D'Amelio et al. disclosure itself, in addition to Figs. 13-16 and 19, Fig. 3 is set out for convenience below. Fig. 3 gives an overview of the two major components of the D'Amelio et al. device.

FIG. 3.



As can be seen from Fig. 3, the D'Amelio et al. device includes an inner portion (borescope 34) which is designed to be rotatable (as indicated by the arrows) with respect to an outer guide member 36. Figs. 13-16 and 19, on the other hand, illustrate various ways in which the D'Amelio et al. device is used.

FIG. 13.

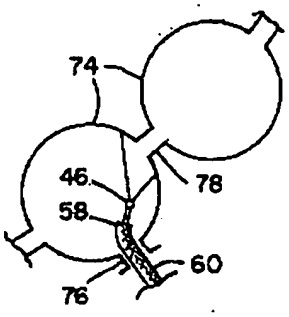


FIG. 14.

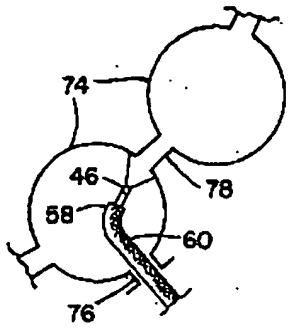


FIG. 15.

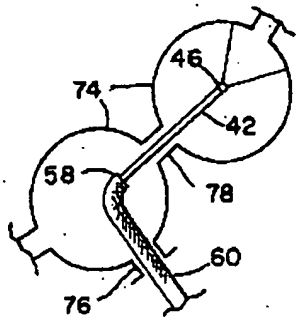


FIG. 16.

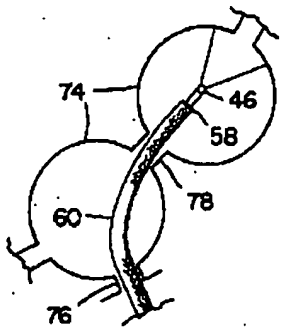
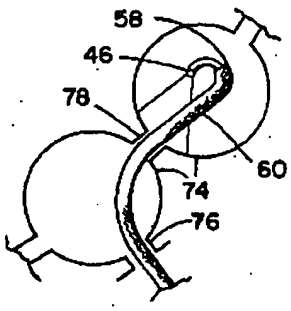


FIG. 19.



Note that claimed inventions are very different from D'Amelio et al. D'Amelio et al. is indifferent to the shapes formed by the apparatus since the D'Amelio device has direct information as to the direction in which the device is pointing. (The entire purpose of D'Amelio et al. is to point an optical inspection apparatus toward the area of interest.)

Costella, cited by the Examiner apparently as an alternative to D'Amelio, adds nothing. Perhaps the Examiner recognizes this, since although the first sentence of paragraph 8 of the Office action cites Costella it is never actually **applied** in the rejection. It is extremely unfair to make the applicant guess as to the rejection, but in the interest of completeness, applicant will discuss Costella. Costella is very similar to D'Amelio et al. in that it is directed to "apparatus and method . . . to inspect the interior of a construction such as a vessel, piping, machinery and the like, including jet engine combustion cans." Abstract, first sentence. At col. 8, lines 30-34, Costella discloses "using articulating means capable of moving one or both of the probe and guide insertion tube in four directions also would lend the device to many different applications." Applicant takes this passage to mean that either the probe or the guide insertion tube separately can be moved in one of four directions as desired, or that both the probe and guide insertion tube jointly can be moved in one of four directions as desired. Under either construction of this language, there is no hint in Costella that any **out-of-plane shapes** can be, or should be constructed. In fact, in view of the express teaching of the very similar D'Amelio et al. reference to avoid out-of-plane shapes, the Examiner's suggested combination of Costella and D'Amelio et al. must teach avoiding out-of-plane shapes as well.

With the present invention, all shapes desired can be achieved with two curved (or curvable) elements, each of which bends in only one plane. Costella contemplates a very different device in which probes and guide tubes are movable in four different directions. Moreover, there is absolutely no disclosure in Costella of out-of-plane configurations as required by the present claims. Costella appears to teach that if you need to point in a particular direction, you simply rotate the probe or guide tube in that direction and bend

the probe or guide tube if necessary. Costella does not even hint that by bending the probe and the guide tube at right angles one can obtain an out-of-plane configuration. Nor is there any indication in Costella that such a configuration would be desirable. (And, as discussed above, the combination of Costella and D'Amelio et al. clearly lacks such a feature given the D'Amelio et al. reference's express teaching against such a configuration.

Therefore, the out-of-plane feature of the present claims is not shown or suggested by Costella. Moreover, several of these claims, as discussed below, require fixing the inner medical element translationally with respect to the catheter tube. Costella, however, has no translational fixing (although it does have rotational fixing by means of locking screw 13).

Turning to the claims, claim 10 requires, inter alia, a catheter tube with a distal end portion fixed in a first curve (that defines a first plane), and fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed **substantially out of the first plane** for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

As can be seen from the drawings in D'Amelio et al., there are first and second curves as defined in claim 10 only when one is attempting to look back at the entry point into the jet engine can. This is shown in Fig. 19. (Compare Figs. 13-16 in which the inner element is always straight). With respect to Fig. 19, D'Amelio et al. expressly teaches that "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39. ("Guide member 36" referred to in this passage

includes "tubular elongated flexible member 60" shown in Fig. 19—see col. 6, lines 5-8.) D'Amelio et al., therefore, teach directly away from the invention claimed in claim 10. D'Amelio et al. not only teaches it—it demands it, stating that the inner assembly "must" articulate in the same plane as the outer assembly. For all these reasons, the rejection over D'Amelio et al. is baseless. Costella fails to add anything to the rejection of this claim. A combination of D'Amelio et al. and Costella as proposed by the Examiner has to have the feature that D'Amelio et al. says "must" be present—articulation of two curves in the same plane, rather than in two different planes. In fact, no combination of references with D'Amelio et al. can read on claim 10 given the express teaching of D'Amelio et al. on this fundamental feature of the claim. Claim 10 is allowable for all these reasons.

Claims 11 through 16 depend from claim 10 and are allowable therewith. In addition, claim 11 requires fixing the inner medical element rotationally with respect to the catheter tube. As described above in the discussion of D'Amelio et al., D'Amelio et al. does not provide for rotational fixing. In fact, that would be the very antithesis of how D'Amelio et al. works. D'Amelio et al. provides for longitudinal fixing, but not rotational fixing. Claim 11 is allowable for this reason as well.

Claim 15 specifies that the second curve defines a second plane and that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. As discussed above, D'Amelio et al. requires that there be no angle between the plane of the inner element and the plane of the outer element. Certainly, the 90° angle specified in claim 15 is neither disclosed nor taught by these references. Claim 15 is allowable for these reasons as well.

Claim 19 is an independent claim that requires a catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane, and an inner medical element in the catheter tube. The claim further specifies forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As discussed above in connection with claim 10, these references do not show—and in fact teach away from—the method in which the distal end of the combination catheter is disposed "substantially out of the first plane." Claim 19 is, therefore, allowable for exactly the same reasons as claim 10.

Claims 20-22, 24 and 26 all relate back to claim 19 and are allowable for the same reasons as that claim. Claim 24, in addition, requires proximally fixing the distal end of the combination catheter substantially out of the first plane. Since these references teach away from forming such an out-of-plane shape, they also teach away from fixing the combination catheter in that shape. Claim 26 also provides for proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed above, D'Amelio et al. fixes against translation but not rotation. In fact fixation against rotation is undesirable in D'Amelio et al. because of how the device is used. Any combination of references with D'Amelio et al., therefore, cannot include the required proximal fixing against rotation of claim 26. Claims 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent claim. It includes the out-of-plane feature discussed above in connection with claims 10 and 19, and the proximal fixing against

rotation (and translation) feature discussed above in connection with claim 26. It is allowable over these references, therefore, for the same reasons as both those claims.

Claim 29 is an independent claim that requires not only the forming of a first out-of-plane configuration, but also a second. It also requires proximal fixation against rotation (and translation) during those times when the distal end portion of the combination catheter is in the first out-of-plane configuration, and during those times when it is in the second out-of-plane configuration. These references do not teach a single out-of-plane configuration, much less two. Nor does this combination teach the requisite proximal fixing against rotation. Claim 29 is allowable for all these reasons.

Claims 31, 33 and 34 depend from claim 10 and are allowable therewith. Claim 31 further requires that the second curve is disposed substantially out of the first plane by rotating the inner medical element with respect to the catheter tube. D'Amelio et al., as explained above, teaches away form making such an out-of-plane shape, so it certainly also teaches away from rotating the inner medical element with respect to the catheter tube in order to make such a (prohibited) shape. Claim 31 is also allowable for these reasons. Claim 33 provides that the fixing step includes proximally fixing the distal end of the combination catheter substantially out of the first plane. This feature, as discussed above in connection with claim 11 is absent from this art. Claim 34 specifies that the inner medical element is proximally fixed against translation and rotation with respect to the catheter tube. As discussed above, this feature is also absent from this combination. Claim 34 is also allowable for this reason.

Claim 32 depends form claim 19 and is allowable for the same reasons as that claim.

CONCLUSION

In summary, the claims on appeal are directed to methods of manipulating a combination catheter to achieve out-of-plane shapes that are not merely transitory, but rather deliberately formed and maintained so that the inner element or the combination catheter itself can be used for a medical purpose. This feature is absolutely fundamental, and is found only in the present disclosure. That the prior art lacks this feature is shown, in part, by the multiple alternative obviousness rejections, using an even larger number of references.

Six rejections using ten references speaks eloquently to the fact that the Examiner has not, and cannot, find the presently claimed inventions in the prior art. This feature, absent from the art, provides shapes for specific purposes, such as anchorage or wedging of the catheter in a desired location, which heretofore have required specially designed preformed catheter shapes to achieve.

The prior art is very different. Sylvanowicz points to the left or right coronary arteries and extends an inner catheter toward the ostia using respective planar shapes with one functionally straight element and one curved element (Syl., col. 7, ll. 46-52). The inner catheter and outer tube in Sylvanowicz are co-linear at the point where the inner catheter exits the outer tube. Both are specified as pointing to the right coronary ostium. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the rights coronary ostium, then those two elements **must be in the same plane**. The Examiner's position to the contrary is not well-taken. Petruzzi points to the ampulla of Vater and a catheter is extended from the distal tip in the plane of sight out the device into the common bile duct, using one

functionally straight element and one curved element (Pet., col. 1, ll. 59-62). The catheter in Cho is pointed in a right-hand lateral or left-hand lateral direction in a single plane of a body cavity with one straight and one curved element (Cho, col. 4, ll. 60-68, col. 5, ll. 1-9). D'Amelio points backward to inspect (in Fig. 19) two curved elements that are specifically required to be in plane. In D'Amelio, either element could have more or less curvature than is shown in Fig. 19—the exact shape of the combination being unknown and unknowable in D'Amelio, since the only feature of importance in that reference is whether the desired area of inspection is in view. This is very different from the present invention where the goal is the out-of-plane shape, not the direction of pointing. (D'Am., col. 8, ll. 34-39). Moreover, the endoscopic art (including Petruzzi, Cho and D'Amelio) provide stable, **stationary** platforms from which an inner element is **moved** to a desired location. The present invention, on the other hand, is directed to inner elements that are **fixed** and maintained in an out-of-plane shape with respect to the outer element. Note that if the inner curved element in the present invention were moved with respect to the outer tube after the shape was formed, it would no longer be "fixed" in the out-of-plane shape. It would have moved to a different, out-of-plane shape with respect to the outer tube. **The present invention and the endoscopy art are simply two different things entirely.**

Shaping, particularly to fix a desired out-of-plane shape into the combination catheter for use in a medical procedure, is the clear distinction of the present invention over the prior art. The present invention is not directed to pointing, aiming, guiding, or steering. The prior art is, but the present invention is not. This distinction, and the

invention itself, are fully and clearly articulated in the following passages from the present specification:

> "As will become apparent in view of the following disclosure, manipulation of catheter 31 results in mimicking virtually any simple or complex curved configuration of selective arterial catheter shape imaginable while the catheter is disposed in the patient." Page 8, lines 18-20.
>
> "Tip reorientation, the goal of most prior devices which have addressed the problem, is only half of what is needed to make a truly workable universal catheter. Numerous catheter configurations have been conceived not only to reorient the tip properly for selection of branch vessels, but also to provide anchorage of the catheter against the aortic wall." Page 1, lines 24-27
>
> "These complex configurations, therefore, evolved not only to orient the tip properly, but also to wedge the catheter securely in the branch vessel. Other devices which simply modify the distal catheter curve may aid in tip orientation for vessel selection, but fail to provide the anchorage which is necessary to prevent catheter dislodgement." Page 2, lines 6-9.

All the prior art except Cho points with a proximal element and moves the distal element to perform a medical procedure. The proximal and distal elements are not "fixed" together—rather each performs its own function separately. Cho fixes two elements together and then uses them as a unit, but Cho uses a functionally straight element and a curved element which are always in plane with respect to each other, and which as a unit move with respect to a gastroscope (that is, the two elements in Cho are not fixed in shape with respect to the gastroscope). The art, in general, points with one (usually

straight) element and moves the other to carry out a medical procedure. The presently claimed invention forms shapes with two curved elements and uses the out-of-plane formed shape of the combination to carry out a medical procedure. That is, in the present invention, the two elements are fixed relative to one another in the combination out-of-plane shape and then used in the medical procedure (which can include moving the combination as a unit with a particular shape to a desired location).

The presently claimed invention constitutes a new, nonobvious and useful method—a true invention. This invention is not shown or suggested in the prior art. Any one of the following features of the present claims would be sufficient to distinguish the art:

- two curved elements interacting and
- fixed together
- to form an out-of-plane shape
- which out-of-plane shape is used in a medical procedure.

Many of the claims include several of them. The claims are allowable over this art.

Given the Office's renewed **emphasis on the independent inventor and increased quality in examination**, all six of these rejections should be overturned.

Reversal of the Examiner, therefore, is solicited.

IX. APPENDIX OF CLAIMS

The text of the claims involved in the appeal is as follows:

10. The method of forming the shape of a combination catheter comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end portion;

fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

medically using at least one of the catheter tube or the inner medical element while the distal end of the inner medical element is disposed substantially out of the first plane.

11. The method as set forth in claim 10 further including fixing the inner medical element rotationally with respect to the catheter tube.

12. The method as set forth in claim 10 wherein at least one of the catheter tube and the inner medical element have curves preformed in their distal end portions.

13. The method as set forth in claim 10 wherein at least one of the catheter tube and the inner medical element are remotely controllable to form curves in their distal end portions.

14. The method as set forth in claim 10 wherein the first curve has a first radius of curvature and the second curve has a second radius of curvature, both curves being disposed a distance from the respective distal ends of the catheter tube and the inner medical element not substantially greater than three times the smaller of the first and second radii of curvature, further including the step of separating the first and second curves in operation by no more than three times the smaller of the first and second radii of curvature.

15. The method as set forth in claim 10 wherein the second curve defines a second plane, the first plane being fixed at an angle of approximately ninety degrees with respect to the second plane.

16. The method as set forth in claim 10 wherein the first curve has a first arc length and the second curve has a second arc length, each curve being disposed from the distal end of its corresponding tube or element respectively a distance no greater than three times the smaller of the first and second arc lengths, further including the step of separating the first and second curves in operation by no more than three times the smaller of the first and second arc lengths.

19. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

20. The method of using a combination catheter as set forth in claim 19 further including the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane.

21. The method of using a combination catheter as set forth in claim 20 further including the step of reforming the distal end of the combination catheter into a substantially different shape.

22. The method of using a combination catheter as set forth in claim 21 further including the step of using the combination catheter in a medical procedure while the distal end of the combination catheter is in the reformed shape.

24. The method as set forth in claim 19 further including proximally fixing the distal end of the combination catheter substantially out of the first plane.

26. The method as set forth in claim 19 further including proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

28. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element; and

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

29. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a first shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed substantially out of the first plane;

forming the combination catheter into a second shape, different from the first shape, in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed in the second shape.

31. The method as set forth in claim 10 wherein the second curve is disposed substantially out of the first plane by rotating the inner medical element with respect to the catheter tube.

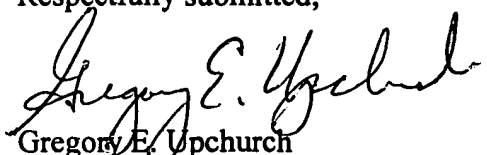
32. The method as set forth in claim 19 wherein the forming step includes rotating the inner medical element with respect to the catheter tube.

33. The method as set forth in claim 10 wherein the step of fixing includes proximally fixing the distal end of the combination catheter substantially out of the first plane.

34. The method as set forth in claim 10 wherein the step of fixing includes proximally fixing the inner medical element against translation and rotation with respect to the catheter tube.

The Office is hereby authorized to charge deposit account #08-3460 for any additional fees required.

Respectfully submitted,



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